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Dated: May 15, 1995.

Gary J. Dykstra,

Acting Associate Commissioner for
Regulatory Affairs.

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[Docket No. 95E-0055]

**Determination of Regulatory Review
Period for Purposes of Patent
Extension; FRAGMIN®**AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FRAGMIN® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product FRAGMIN® (dalteparin sodium). FRAGMIN® is indicated for prophylaxis against deep vein thrombosis, which may lead to pulmonary embolism, in patients undergoing abdominal surgery who are at risk for thromboembolic complications. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FRAGMIN® (U.S. Patent No. 4,303,651) from Pharmacia Aktiebolag, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 23, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FRAGMIN® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FRAGMIN® is 3,555 days. Of this time, 2,832 days occurred during the testing phase of the regulatory review period, while 723 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* March 31, 1985. The applicant did not state an investigational new drug application (IND) effective date, stating that foreign studies were used in lieu of an IND. However, FDA records indicate that certain studies material to the approval of the product were conducted under IND 25,924. Therefore, the IND effective date was March 31, 1985, which was 30 days after FDA receipt of IND 25,924.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 30, 1992. The applicant claims February 28, 1993, as

the date the new drug application (NDA) for FRAGMIN® (NDA 20-287) was initially submitted, whereas it is actually the filing date. FDA records indicate that NDA 20-287 was refused to file on September 25, 1992. The correct resubmission date for NDA 20-287 is December 30, 1992, which was the date the resubmission was actually received by the agency. Therefore, the NDA initial submission date for NDA 20-287 is December 30, 1992, the same as the resubmission date.

3. *The date the application was approved:* December 22, 1994. FDA has verified the applicant's claim that NDA 20-287 was approved on December 22, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 661 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may on or before July 25, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 22, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 15, 1995

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

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